MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068
Phone: (973) 228-9898 - Fax: (973) 228-0303
www.mazieslater.com

David A. Mazie*
Adam M. Slater*°
Eric D. Katz*°
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn°
David M. Estes

*Certified by the Supreme Court of New Jersey as a Civil Trial Attorney

°Member of N.J. & N.Y. Bars

Writer's Direct Dial:
(973) 228-0454
Writer's Email:
aslater@mazieslater.com

Karen G. Kelsen°
Cheryll A. Calderon
Adam M. Epstein°
Cory J. Rothbort*°
Michael R. Griffith°
Christopher J. Geddis
Alexander Q. Reynoso
Samuel G. Wildman
Julia S. Slater°

April 6, 2021

VIA ECF & EMAIL
TIV@stevenslee.com
Hon. Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Vanaskie:

Please accept this letter on behalf of the Plaintiffs in response to ZHP's request for translation of English documents to Mandarin for use at depositions of ZHP witnesses who do not read or speak English.[1]

As an initial matter, Plaintiffs do not believe that Defendant has established good cause to require a change to the existing protocol. After the parties' conference with the Court on Thursday, April 1, 2021, Plaintiffs were able to complete the deposition of ZHP witness, Peng Dong, using both English and Chinese documents without issue. Attached as Exhibit A are excerpts from the

[1] Plaintiffs would appreciate it if ZHP's counsel would cease accusations of discrimination of any nature. ZHP's brief on this issue is now the second time that claim has been made and it is no more appropriate now than it was last week.

Peng Dong deposition demonstrating that the questioning was neither difficult or unfair for the witness.[2] The only difficulty in the questioning was the result of the failure by the witness to testify responsively. Plaintiffs are generally only asking about short specific excerpts from these documents, and the interpreter is, and has been, perfectly capable of translating those excerpts, along with any other sections that the witness may wish to read.

Further, it is important to recognize that not all English language documents are the same, nor do they all raise the same issues. The Court, as cited by Defendants, expressed a concern about what information is provided to a witness who has not had the opportunity to review the document. (3/29/21 Tr. 30:13-31:1, Ex. B hereto). In the event that any translations are directed, the scope should be narrowly drawn. For example, it is not reasonable to require English language documents authored or received by the deponent in the ordinary course of business, and those that are located in the witness's custodial file, to be translated to Mandarin. These documents would have presumably been sent or received by the witness in the ordinary course and the burden should not be on Plaintiffs to translate those documents. In this situation, the witness had the opportunity to review the document in the ordinary course of business. This is especially true for email communications where the witness is either a sender of the English language email, or a recipient of the English language email. The fact that the email is in English demonstrates that was sufficient – if it were not, a Mandarin translation would exist.

ZHP however has obstructed Plaintiffs' ability to proceed even with emails sent or received in English. During the deposition of Minli Zhang, taken for Plaintiffs by Layne Hilton, ZHP

[2] In accordance with the Confidentiality and Protective Order, Plaintiffs will not file these deposition excerpts or the others referenced below on ECF. However, Plaintiffs will send them to the Court via email with a courtesy copy of this letter.

defense counsel Jessica Priselac repeatedly blocked Ms. Hilton from asking basic foundational questions about an English language email *written by the witness herself*, interrupted the questioning to direct the witness to request translation of the entire document in question, and even instructed the witness not to answer questions on certain occasions.[3] Plaintiffs attach an excerpt demonstrating this issue as Exhibit C hereto. Plaintiffs are entitled to question witnesses about their own English language documents in order to establish basic foundational information such as whether the witness wrote that email, how the witness would go about writing that English language email, and who assisted the witness with writing that English language email.

Furthermore, Plaintiffs must be allowed to question witnesses about their understanding of key corporate documents such as contracts and standard management procedures that have been kept in the ordinary course of business in English without having to produce an informal, Chinese language translation. Current Good Manufacturing Practices ("cGMPs") require that certain documents be kept and maintained, including contracts (such as supplier agreements), quality standards, and standard operating procedures. To the extent ZHP only keeps English language versions of these key business documents, Plaintiffs' must be afforded an opportunity to question the witness on how the Company understands the terms and provisions of those documents without a formal translation. Again, if ZHP did not deem it necessary to translate the document, then it should not need to be translated for a deposition.[4] For example, during the deposition of Minli Zhang, Ms. Zhang testified that, despite a key contract being only maintained in English, she still

[3] While ZHP has repeatedly touted Ms. Zhang's deposition as an example for how depositions *should* be handled, Plaintiffs note defense counsel's instruction to the corporate witness not to answer the question, "did you write this email?," which was not appropriate.

[4] It goes without saying that Plaintiffs should not be required to produce informal Chinese translations for documents that ZHP itself does not believe need to be translated into Chinese and kept in the ordinary course of business.

had her "basic understanding of this document, based on how I read it and how I used it." (Ex. A at 134:3-4, Ex. D hereto). Plaintiffs then proceeded to ask further questions about Ms. Zhang's basic understanding of the document, as well as foundational and discovery questions about the identity of other employees who assisted Ms. Zhang with translating the document when Ms. Zhang's job responsibilities required her to review the terms of the contract. *Id.* Questions about how witnesses understand their own documents are certainly proper questions to be asked at a deposition.

Plaintiffs should likewise not be required to translate official FDA communications and documents. Pursuant to 21 Code of Federal Regulations section 803.13(a) (English Reporting Requirement), all reports required in this part which are submitted in writing or electronic equivalent shall be submitted to the FDA in English. Chapter 1 of the U.S. FDA Investigation Operation Manual (IOM) states the following:

> SUBCHAPTER 1.1 - ENGLISH LANGUAGE REQUIREMENT FOR FDA DOCUMENTS
>
> Records or Federal Records are defined in 44 U.S.C. 3301 as including "all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics which includes regulatory notes, memoranda, inspection reports, emails, and official government forms e.g. SF-71, FDA-482-FDA-483, etc. made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government or because of the informational value of the data in them (44 U.S.C. 3301). (See also § 1222.10 of this part for an explanation of this definition). **All official FDA documents generated during your routine duties shall be completed in English. This requirement is necessary to facilitate efficiency in the workplace. For instance, many of your work products used in support of FDA's regulatory process are subject to review and auditing by your supervisor, utilized by your co-workers, and others, including the public, in that they are releasable under the Freedom of Information Act (FOIA). The Agency does not have the resources**

> **to assure the accurate and timely English translation of documents written in a non-English language in order to facilitate their use in the conduct of official business. English is generally considered to be the common language of the U.S.; therefore it is necessary to standardize the language utilized in the production of official FDA documents.** Additionally, FDA imposes English only requirements on the public for information submitted to the Agency. For example 21 Code of Federal Regulations section 803.13(a) (English Reporting Requirement) states that all reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

Since the core of this case deals directly with issues related to the FDA, communications with the FDA, and the FDA's correspondence and guidance, Plaintiffs should not be required to translate the documentation arising from the regulatory process, into Mandarin. This is especially true in light of the fact that ZHP was required to submit these documents to the FDA in English, and to review and understand the FDA communications written in English as well. **In fact, presumably, at some point these documents were explained to the ZHP witnesses or they have already been translated for their benefit**. **Plaintiffs request that these translations be ordered produced immediately so that Plaintiffs are not being asked to do what ZHP has already done - regardless of when the translations were created – so that Plaintiffs need not translate any page that has already been translated**.[5]

[5] ZHP now chastises Plaintiffs for using three English documents during Peng Dong's deposition when ZHP produced Chinese versions of those documents. In fact, Plaintiffs used Chinese versions of two of those exhibits during the deposition (Ex. 219 was a Chinese version of Ex. 218, and Ex. 221 was a Chinese version of Ex. 220). (*See* 4/2/2021 Tr. 475-76, Ex. A hereto). Although Plaintiffs had not identified ZHP's translation of Ex. 213, that line of questioning went smoothly, and ZHP certainly had the ability to point out the Chinese translation in its production when that exhibit was entered. Furthermore, Plaintiffs' efforts have been hampered in identifying the internal translations because ZHP has not produced any metadata that linked ZHP's own Chinese translations with the English language document. Indeed, in negotiating the ESI protocol, ZHP refused to make a metadata link between English and Chinese documents, arguing it would be too burdensome for them to do so. Now they are demanding that Plaintiffs do that very thing.

If the Court requires Plaintiffs to provide any translations from English to Mandarin during depositions, this obligation should be narrow, for the reasons set forth above. Plaintiffs should only be required to provide a translation of the page in question, and if in a large document, the prior and subsequent page for surrounding context. Translation of the entire documents is not necessary and would be burdensome and unreasonable, especially since most of the document will not be referenced. Plaintiffs have determined that the most reasonable alternative is machine translation, through a service provider such as Google. Defendants previously requested machine translation and now have reiterated that request. Defendants are aware of the fact that there is no guarantee of 100% accuracy, nor the ability to preserve proper formatting and page sequencing, however by requesting this relief Defendants presumably have waived any foundation objections. If needed, ZHP can ask its interpreter to fill in blanks or clarify the translation as needed.

Manual/human translation would be extremely burdensome, time consuming, and expensive, and should not be ordered. Machine translation is significantly more time and cost efficient than manual/human translation. A significant amount of time and resources would have to be expended by our deposition preparation teams, diverting our Mandarin language reviewers from the ongoing review of the mass of Mandarin language documents for the ongoing string of ZHP depositions. In addition to the added cost in the thousands of dollars (manual translation is time consuming), Plaintiffs are already spending substantial amounts for Mandarin language reviewers and translators just to be able to understand ZHP's Mandarin document production. This support is critical to Plaintiffs' ability to conduct the ZHP depositions. Requiring Plaintiffs to pull those individuals off their work and require them to translate English language documents into Chinese for the convenience of ZHP would thus result in significant prejudice to Plaintiffs.

Further, in order to properly manually translate just a few pages of text, including reproducing the formatting and graphics in the translated version, it can take multiple hours, at a cost of over $100/hour of translator time, and that is for uncertified translations. Certified translations would cost significantly more. Neither the expenditure of such time, nor the cost, is necessary or justified when the current method of allowing the interpreter to translate documents as needed at deposition is working. At most, only the relevant page(s) from a limited category of documents should be machine translated.

For the foregoing reasons, Plaintiffs request that the Court find that ZHP has not shown good cause to modify the fact deposition protocol. If any translations are ordered, Plaintiffs request that this be directed only to a narrow category of documents and in a way that does not unfairly burden Plaintiffs.

Respectfully,

Adam M. Slater